IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Patton et al. Application No: 10/693,318 Confirmation No: 8226 Filed: October 24, 2003 Title: METHOD AND DEVICE FOR DELIVERING AEROSOLIZED MEDICAMENTS	Group Art Unit: 3771 Examiner: Matter, Kristen Clarette Attorney Docket No: 53207-US-CNT[4] (0001.13) March 23, 2009 San Francisco, California 94107

SUPPLEMENTAL APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Notification of Non-Compliant Brief dated January 23, 2009, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby submits a supplemental appeal within two months thereof to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection dated June 20, 2008.

Certificate of Transmission

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By: Melanie Hitchcock
Melanie Hitchcock

Date: March 23, 2009

(1) *Real Party in Interest*

The real party in interest of the present application is Novartis AG (by way of assignment from Novartis Pharmaceuticals AG and from Nektar Therapeutics, which was formerly Inhale Therapeutic Systems, Inc.), having a place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

(2) *Related Appeals and Interferences*

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) *Status of Claims*

Claims 2-39 are presently pending in the case. Claims 2-39 have been finally rejected. The rejection of each of claims 2-39 is hereby appealed.

Claim 1 has been cancelled.

(4) *Status of Amendments*

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

(5) *Summary of the Claimed Subject Matter*

As recited in claim 2 and shown in Figures 3-8, an apparatus for producing aerosolized medicament comprises a reservoir (page 9 lines 13-14) containing a powder medicament (M) to be aerosolized, the powder medicament comprising a protein or polypeptide (page 9 lines 6-9). The apparatus also comprises a chamber

(100) comprising first (104) and second (110) air inlets and a mouthpiece (108), wherein the first and second air inlets are oriented so that gas may flow in a vortical flow path in the chamber (100) and may flow out of the chamber (100) through the mouthpiece (108) and wherein the flow of gas aerosolizes the powder medicament. As discussed on page 5 lines 1-12, at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber (100) for delivery through the mouthpiece (108).

As recited in claim 11 and shown in Figures 3-8, an apparatus for producing aerosolized medicament comprises a reservoir (page 9 lines 13-14) containing a powder medicament (M) to be aerosolized, the powder medicament comprising a protein or polypeptide (page 9 lines 6-9). The apparatus also comprises a chamber (100) comprising first (104) and second (110) air inlets and a mouthpiece (108), wherein the first and second air inlets are oriented so that gas may flow in a vortical flow path in the chamber (100) and may flow out of the chamber (100) through the mouthpiece (108) and wherein the flow of gas aerosolizes the powder medicament. As shown in the table on page 20, the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber (100).

As recited in claim 26 and shown in Figures 3-8, an apparatus for producing aerosolized medicament comprises a reservoir (page 9 lines 13-14) containing a powder medicament (M) to be aerosolized, the powder medicament comprising a systemically therapeutic protein or polypeptide (page 9 lines 6-9). The apparatus also comprises a chamber (100) comprising an air inlet (104) and a mouthpiece (108), wherein the air inlet (104) is oriented so that gas may flow in a vortical flow path in the chamber (108) and may flow out of the chamber (100) through the mouthpiece (108) and wherein the flow of gas aerosolizes the powder medicament. As discussed on page 5 lines 1-12, at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

As recited in claim 35 and shown in Figures 3-8, an apparatus for producing aerosolized medicament comprises a reservoir (page 9 lines 13-14) containing a

powder medicament (M) to be aerosolized, the powder medicament comprising a protein or polypeptide (page 9 lines 6-9). The apparatus also comprises a chamber (100) comprising a tangentially oriented air inlet (104) and a non-tangentially oriented air inlet (110) and a mouthpiece (108), wherein gas may flow into the chamber through the air inlets and may flow out of the chamber (100) through the mouthpiece (108) and wherein the flow of gas aerosolizes the powder medicament. As discussed on page 5 lines 1-12, at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

(6) *Grounds of Rejection to be Reviewed on Appeal*

Appellant requests review of the Examiner's following grounds of rejection:

Claims 2, 5-7, 9-11, 14-16, 18-20, 23, 26, 27, 30, 31, 33 and 34 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,522,383 to Calvert et al (hereinafter Calvert et al) in view of U.S. Patent 4,022,224 to Saifer et al (hereinafter Saifer et al). [Note that the Final Office Action states that claims 14-26 are rejected, but Appellant assumes this was a typographical error and 14-16 was intended.]

Claims 3, 12 and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al and Saifer et al, and further in view of U.S. Patent 4,174,712 to Moren et al (hereinafter Moren et al).

Claims 4, 8, 13, 17, 29 and 32 have been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al and Saifer et al, and further in view of U.S. Patent 3,809,084 to Hansen (hereinafter Hansen).

Claims 21, 24, 35-37 and 39 have been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al and Saifer et al, and further in view of U.S. Patent 4,396,152 to Abplanalp (hereinafter Abplanalp).

Claims 22 and 25 have been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al and Saifer et al, and further in view of U.S. Patent 4,860,740 to Kirk et al (hereinafter Kirk et al).

Claim 38 has been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al, Saifer et al and Abplanalp and further in view of Hansen.

(7) *Argument*

Appellant believes each of claims 2-39 are improperly rejected and are therefore allowable for the following reasons.

The rejections based on Calvert et al and Saifer et al are improper

Independent Claim 2

The Examiner's rejection of independent claim 2 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al in view of Saifer et al is improper and should be reversed.

Calvert et al and Saifer et al do not render claim 2 unpatentable under 35 U.S.C. 103(a). Claim 2 is to an apparatus comprising, inter alia, a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide, and a chamber wherein inlets are oriented so that gas may flow in a vortical flow path in the chamber and wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through a mouthpiece. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Calvert et al and Saifer et al in a manner that would arrive at the invention of claim 2 as will be described.

First, the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a). The Examiner posits that Calvert et al teaches a powder inhaler and that Saifer et al teaches a powder protein (orgotein). The Examiner goes on to contend that one of ordinary skill in the art at the time the invention was made would have found it obvious to substitute the Saifer et al powder protein for the powder delivered in the Calvert et al device. However, the Examiner's proposed modification fails to render claim 2 unpatentable. Even assuming the teachings of Calvert et al and Saifer et al are combinable (which they are not, as discussed below), the system that would result from the proposed modification would not meet all the limitations of claim 2. For example, claim 2 recites "wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece." Nowhere in either reference is this amount of suspension discussed. Since all limitations of claim 2 are not met by the proposed combination of references, the Examiner has failed to establish a prima facie case under 35 U.S.C. 103(a), and claim 2 is not rendered unpatentable by the references.

In reference to this limitation, the Examiner points to column 4 lines 35-55 of Calvert et al, but a close reading of this section of the reference reveals nothing more than a teaching that a high degree of emptying is desirable. The Examiner states that the suspension of large amounts of powder would have been "desirable" and therefore obvious to one of ordinary skill in the art. Appellant disagrees that this statement serves to render claim 2 unpatentable. Desirability does not make something so. Perpetual motion machines and cures for cancer are "desirable." Thus the alleged desirability of suspending large amounts of powder does not mean that the use of Saifer et al's powder in the Calvert et al device would result in a combination where the degree of suspension is that which is claimed in claim 2. In actuality, there is no mention of the degree of aerosolization that is achieved in Calvert et al. The achievement of 40% suspension for delivery through the mouthpiece, as recited in claim 2, is no small feat. Furthermore, all powders behave differently. A change in active agents within a powder will cause a change in powder characteristics. This change is likely to even be more

exacerbated when going from a non-protein active agent to a protein active agent, which are difficult to suspend. Accordingly, the Examiner's apparent contention that by merely substituting the protein powder taught by Saifer et al for the powder used in Calvert et al would necessarily result in a system that meets the limitations of claim 2 is entirely without basis and is purely speculative. Moreover, the Examiner offers no support for the contention that suspension of large amounts of powder would have been desirable. In drug delivery practice and particularly in the aerosolized drug delivery practice, reproducibility and consistency are often paramount. In many cases, efficiency will be sacrificed for reproducibility and consistency of dosing.

In addition to the failure to establish a prima facie case, the teachings of Calvert et al and Saifer et al are not properly combinable under 35 U.S.C. 103(a) in that there is no teaching, suggestion, or motivation to combine the teachings of the references. There is nothing within the references to suggest to a person of ordinary skill in the art that combining the teachings of the references would be desirable. Actually, the opposite is the case. One of ordinary skill in the art would be steered away from the proposed combination when the person of ordinary skill in the art considers the teachings of the references as a whole. For example, in the examples given by Saifer et al in columns 5 and 6, no example utilizes a powder inhaler formulation of the protein powder. Instead, all examples suggest using only a nebulized or pressurized aerosol type of formulation (see column 5 line 47-48). The dry powder preparation of Preparation 3 is ignored in the examples and this is clearly nothing more than a prophetic mention. Dry powder protein formulations are notoriously difficult to formulate in a manner that maintains stability. Accordingly, one of ordinary skill in the art after considering the teachings of Saifer et al ***as a whole*** would not have been motivated to use the Saifer et al teachings in a dry powder inhaler in place of the exemplified versions of Saifer et al. Moreover, it would not have then been obvious to select the Calvert et al device out of the numerous dry powder inhalers that were known at the time. The proposed combination is therefore additionally based entirely on impermissible hindsight reasoning and is not based on suggestions and motivations provided by the references themselves. Still further, there is no reasonable likelihood of

success considering that Saifer et al fails to show that its dry powder is dispersible in a dry powder inhaler.

Furthermore, in addition to there being no teaching, suggestion, or motivation to combine Calvert et al and Saifer et al, the proposed modification is not one that is well within the grasp of a person having ordinary skill in the art. First, the Examiner has not demonstrated that there was a known problem for which there was an obvious solution encompassed by the claims. To the contrary, the teachings of the references give no indication that there was a problem associated with either teaching. It is not permissible to use the Applicant's disclosure of a problem as a motivation to provide a solution. Second, this is not a situation where it would have been "obvious to try." In order for an "obvious to try" rejection to be proper, it must be shown that there was a design need or market pressure to solve a problem and that there were a finite number of identified, predictable solutions. KSR v. Teleflex, 127 S. Ct. 1727 (2007). The Examiner has provided neither in the present case. There was no demonstrated design need or market pressure to solve a problem that would have been overcome by the proposed combination. Also, given the number of dry powder inhalers that were known and given the limitless formulation choices available, there was not a finite number of identified, predictable solutions available. Accordingly, this is not a situation where a person having ordinary skill in the art at the time the invention was made would have seen the benefit of combining the references in the proposed manner.

Finally, secondary considerations dislodge any determination that claim 2 might have been obvious. The ability to deliver high value medicaments such as proteins and polypeptides efficiently and effectively is both novel and unexpected, as discussed in the present specification on pages 1-4. These unexpected results are but an example of secondary considerations that demonstrate the nonobviousness of claim 2.

For at least these reasons, claim 2 is not properly rejectable under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al, and Appellant requests reversal of the rejection.

Claims depending from Claim 2

The Examiner's rejection of dependent claims 5-7, 9, 10 and 20 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al in view of Saifer et al is improper and should be reversed. Claims 5-7, 9, 10 and 20 depend from independent claim 2. Independent claim 2 is not rendered unpatentable by Calvert et al and Saifer et al, as discussed above. Since claims 5-7, 9, 10 and 20 include all of the limitations of the claim from which they depend, claims 5-7, 9, 10 and 20 are not rendered unpatentable by Calvert et al and Saifer et al for at least the same reasons as claim 2. Reversal is requested.

Independent Claim 11

The Examiner's rejection of independent claim 11 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al in view of Saifer et al is improper and should be reversed.

Claim 11 is to an apparatus comprising, inter alia, a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide and a chamber wherein inlets are oriented so that gas may flow in a vortical flow path in the chamber and wherein the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber. Calvert et al and Saifer et al do not teach this combination of features. Neither Calvert et al nor Saifer et al teaches a volume of aerosolized medicament that is from 9.24 percent to 21.5 percent of the volume of the chamber. The Examiner's contention that the claimed volume is "an obvious design consideration" (see page 3 of Final Office Action of September 7, 2007) is without basis. Even if it was obvious to combine the teachings of Calvert et al and Saifer et al (which it is not, as discussed below) and even if it was obvious to make the allegedly "obvious design considerations" (which the Examiner has shown no reason to make), it is purely speculative that any such modification would result in a system that

meets the limitations of claim 11. The Examiner has posed no theoretical problem that the artisan would be trying to solve in making the alleged "obvious design considerations," and the Examiner has also offered no teachings of parameters or variables that would lend themselves to directing the artisan towards a design that might result in Appellant's design. Accordingly, the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a), and independent claim 11 is not properly rejected thereunder.

Additionally, it would not have been obvious to combine the teachings of Calvert et al and Saifer et al as proposed by the Examiner in a manner that would result in the invention of claim 11. First, there is no teaching, suggestion or motivation to combine the references as proposed. There is nothing within the references to suggest to a person of ordinary skill in the art that combining the teachings of the references would be desirable. Actually, the opposite is the case, and one of ordinary skill in the art after considering the teachings of Saifer et al ***as a whole*** would not have been motivated to use a dry powder inhaler in place of the exemplified non-dry-powder aerosols of Saifer et al, as discussed in more detail above in connection with Claim 2. Moreover, the proposed combination is based entirely on impermissible hindsight reasoning and is not based on suggestions and motivations provided by the references themselves, also as discussed above. Still further, there is no reasonable likelihood of success considering that Saifer et al fails to show that its dry powder is dispersible in a dry powder inhaler.

Furthermore, in addition to there being no teaching, suggestion, or motivation to combine Calvert et al and Saifer et al, the proposed modification is not one that is well within the grasp of a person having ordinary skill in the art. First, the Examiner has not demonstrated that there was a known problem for which there was an obvious solution encompassed by the claims. To the contrary, the teachings of the references give no indication that there was a problem associated with either teaching. It is not permissible to use the Applicant's disclosure of a problem as a motivation to provide a solution. Second, this is not a situation where it would have been "obvious to try." In order for an "obvious to try" rejection to be proper, it must be shown that there was a design need or

market pressure to solve a problem and that there were a finite number of identified, predictable solutions. KSR (2007). The Examiner has provided neither in the present case. There was no demonstrated design need or market pressure to solve a problem that would have been overcome by the proposed combination. Also, given the number of dry powder inhalers that were known and given the limitless formulation choices available, there was not a finite number of identified, predictable solutions available. Accordingly, this is not a situation where a person having ordinary skill in the art at the time the invention was made would have seen the benefit of combining the references in the proposed manner.

Finally, secondary considerations dislodge any determination that claim 11 might have been obvious. The ability to deliver high value medicaments such as proteins and polypeptides efficiently and effectively is both novel and unexpected, as discussed in the present specification on pages 1-4. These unexpected results are but an example of secondary considerations that demonstrate the nonobviousness of claim 11.

For at least these reasons, claim 11 is not properly rejectable under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al and Appellant requests reversal of the rejection. Reversal is requested.

Claims depending from Claim 11

The Examiner's rejection of dependent claims 14-16, 18, 19 and 23 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al in view of Saifer et al is improper and should be reversed. Claims 14-16, 18, 19 and 23 depend from independent claim 11. Independent claim 11 is not rendered unpatentable by Calvert et al and Saifer et al, as discussed above. Since claims 14-16, 18, 19 and 23 include all of the limitations of the claim from which they depend, claims 14-16, 18, 19 and 23 are not rendered unpatentable by Calvert et al and Saifer et al for at least the same reasons as claim 11. Reversal is requested.

Independent Claim 26

The Examiner's rejection of independent claim 26 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al in view of Saifer et al is improper and should be reversed.

Claim 26 is to an apparatus comprising, inter alia, a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a systemically therapeutic protein or polypeptide, and a chamber wherein an inlet is oriented so that gas may flow in a vortical flow path in the chamber and wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through a mouthpiece. As discussed above, the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a) in that neither Calvert et al nor Saifer et al teach all of the features set forth in the claim. For example, neither Calvert et al nor Saifer et al teach the suspension of at least 40 percent by weight of the powder medicament. Even if it was obvious to combine the teachings of Calvert et al and Saifer et al (which it is not), it is purely speculative that any such modification would result in a system that meets the limitations of claim 26. Accordingly, the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a), and independent claim 26 is not properly rejected thereunder.

Additionally, it would not have been obvious to combine the teachings of Calvert et al and Saifer et al as proposed by the Examiner in a manner that would result in the invention of claim 26. First, as discussed above, there is no teaching, suggestion or motivation to combine the references as proposed. Secondly, also as discussed above, the proposed modification is not one that is well within the grasp of a person having ordinary skill in the art in that the Examiner has not demonstrated that there was a known problem for which there was an obvious solution encompassed by the claims. This is also not a situation where it would have been "obvious to try." Furthermore, secondary considerations dislodge any determination that claim 26 might have been obvious.

For at least these reasons, claim 26 is not properly rejectable under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al and Appellant requests reversal of the rejection. Reversal is requested.

Claims depending from Claim 26

The Examiner's rejection of dependent claims 27, 30, 31, 33 and 34 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al in view of Saifer et al is improper and should be reversed. Claims 27, 30, 31, 33 and 34 depend from independent claim 26. Independent claim 26 is not rendered unpatentable by Calvert et al and Saifer et al, as discussed above. Since claims 27, 30, 31, 33 and 34 include all of the limitations of the claim from which they depend, claims 27, 30, 31, 33 and 34 are not rendered unpatentable by Calvert et al and Saifer et al for at least the same reasons as claim 26. Reversal is requested.

The rejections based on Calvert et al, Saifer et al and Moren et al are improper

Dependent Claims 3, 12 and 28

The Examiner's rejection of dependent claims 3, 12, and 28 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of Moren et al is improper. Claims 3, 12 and 28 depend from claims 2, 11 and 26, respectively. Claims 2, 11 and 26 are not rendered unpatentable by Calvert et al and Saifer et al as discussed above. Moren et al is not relied upon to make up for the deficiencies of Calvert et al and Saifer et al, nor does it. Accordingly, claims 2, 11 and 26 are allowable over the combination of Calvert et al, Saifer et al and Moren et al, and claims 3, 12 and 28 are allowable over Calvert et al, Saifer et al and Moren et al for at least the same reasons as claims 2, 11 and 26. Appellant requests reversal of the rejection.

The rejections based on Calvert et al, Saifer et al and Hansen are improper

Dependent Claims 4, 8, 13, 17, 29 and 32

The Examiner's rejection of dependent claims 4, 8, 13, 17, 29 and 32 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of Hansen is improper. Claims 4 and 8 depend from independent claim 2; claims 13 and 17 depend from independent claim 11; and claims 29 and 32 depend from claim 26. Claims 2, 11 and 26 are not rendered unpatentable by Calvert et al and Saifer et al as discussed above. Hansen is not relied upon to make up for the deficiencies of Calvert et al and Saifer et al, nor does it. Accordingly, claims 2, 11 and 26 are allowable over the combination of Calvert et al, Saifer et al and Hansen, and claims 4, 8, 13, 17, 17, 29 and 32 are allowable over Calvert et al, Saifer et al and Hansen for at least the same reasons as claims 2, 11 and 26. Reversal is requested.

The rejections based on Calvert et al, Saifer et al and Abplanalp et al are improper

Dependent Claims 21 and 24

The Examiner's rejection of dependent claims 21 and 24 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of Abplanalp et al is improper.

Claims 21 and 24 are not rendered unpatentable by Calvert et al, Saifer et al, and Abplanalp et al. Claims 21 and 24 depend from independent claims 2 and 11, respectively. Claims 2 and 11 are not rendered unpatentable by Calvert et al and Saifer et al as discussed above. Abplanalp et al is not relied upon to make up for the deficiencies of Calvert et al and Saifer et al, nor does it. Accordingly, claims 2 and 11 are allowable over the combination of Calvert et al, Saifer et al, and Abplanalp et al, and claims 21 and 24 are allowable over Calvert et al, Saifer et al and Abplanalp et al for at least the same reasons as claims 2 and 11. Reversal is requested.

Independent Claim 35

The Examiner's rejection of independent claim 35 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of Abplanalp et al is improper.

Claim 35 is to an apparatus comprising, inter alia, a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide, and a chamber wherein an inlet is tangentially oriented and wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through a mouthpiece. Calvert et al, Saifer et al, and Abplanalp do not teach this combination of features. Neither Calvert et al, Saifer et al nor Abplanalp teaches the suspension of at least 40 percent by weight of the powder medicament, as discussed above. Even if it was obvious to combine the teachings of Calvert et al, Saifer et al, and Abplanalp (which it is not), it is purely speculative that any such modification would result in a system that meets the limitations of claim 35. Accordingly, the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a), and independent claim 35 is not properly rejected thereunder.

Additionally, it would not have been obvious to combine the teachings of Calvert et al, Saifer et al and Abplanalp as proposed by the Examiner in a manner that would result in the invention of claim 35. First, as discussed above, there is no teaching, suggestion or motivation to combine the references as proposed. Secondly, also as discussed above, the proposed modification is not one that is well within the grasp of a person having ordinary skill in the art in that the Examiner has not demonstrated that there was a known problem for which there was an obvious solution encompassed by the claims. This is also not a situation where it would have been "obvious to try." Furthermore, secondary considerations dislodge any determination that claim 35 might have been obvious. Still further, one of ordinary skill in the art would not have found it obvious to combine the teachings of Abplanalp's propellant based dispenser with the dry powder inhaler of Calvert et al.

For at least these reasons, claim 35 is not properly rejectable under 35 USC §103(a) as being unpatentable over Calvert et al, Saifer et al and Abplanalp. Reversal is requested.

Dependent Claims 36 and 37

The Examiner's rejection of dependent claims 36 and 37 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of Abplanalp et al is improper. Claims 36 and 37 depend from independent claim 35. Independent claim 35 is not rendered unpatentable by Calvert et al, Saifer et al and Abplanalp et al, as discussed above. Since claims 36 and 37 include all of the limitations of the claim from which they depend, claims 36 and 37 are not rendered unpatentable by Calvert et al, Saifer et al and Abplanalp et al for at least the same reasons as claim 35. Reversal is requested.

Dependent Claim 39

The Examiner's rejection of dependent claim 39 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of Abplanalp et al is improper. Claim 39 depends from independent claim 11. Independent claim 11 is not rendered unpatentable by Calvert et al and Saifer et al, as discussed above. Abplanalp et al is not relied on to make up for the deficiencies of Calvert et al and Saifer et al, nor does it. Accordingly, claim 11 is allowable over the combination of Calvert et al, Saifer et al and Abplanalp et al and claim 39 is not rendered unpatentable by Calvert et al, Saifer et al and Abplanalp et al for at least the same reasons as claim 11. Reversal is requested.

The rejections based on Calvert et al, Saifer et al and Kirk et al are improper

Dependent Claims 22 and 25

The Examiner's rejection of dependent claims 22 and 25 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of Kirk et al is improper. Claims 22 and 25 depend from independent claims 2 and 11, respectively. Claims 2 and 11 are not rendered unpatentable by Calvert et al and Saifer et al as discussed above. Kirk et al is not relied upon to make up for the deficiencies of Calvert et al and Saifer et al, nor does it. Accordingly, claims 2 and 11 are allowable over the combination of Calvert et al, Saifer et al and Kirk et al, and claims 22 and 25 are allowable over Calvert et al, Saifer et al and Kirk et al for at least the same reasons as claims 2 and 11. Reversal is requested.

The rejections based on Calvert et al, Saifer et al, Abplanalp et al and Hansen

Dependent Claim 38

The Examiner's rejection of dependent claim 38 under 35 U.S.C. §103(a) as being unpatentable over Calvert et al, Saifer et al and Abplanalp et al and further in view of Hansen is improper. Claim 38 depends from independent claim 35. Claim 35 is not rendered unpatentable by Calvert et al, Saifer et al and Abplanalp et al as discussed above. Hansen is not relied upon to make up for the deficiencies of Calvert et al, Saifer et al and Abplanalp et al, nor does it. Accordingly, claim 35 is allowable over the combination of Calvert et al, Saifer et al, Abplanalp et al and Hansen, and claim 38 is allowable over Calvert et al, Saifer et al, Abplanalp et al and Hansen for at least the same reasons as claim 35. Reversal is requested.

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: March 23, 2009

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(8) Claims Appendix

2. An apparatus for producing aerosolized medicament, the apparatus comprising:

a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide; and

a chamber comprising first and second air inlets and a mouthpiece, wherein the first and second air inlets are oriented so that gas may flow in a vortical flow path in the chamber and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament,

wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

3. An apparatus according to claim 2 wherein the chamber volume is from 100 ml to 750 ml.

4. An apparatus according to claim 2 further comprising a source of compressed gas, wherein the compressed gas may be released from the source of compressed gas to cause the flow of gas to aerosolize the medicament.

5. An apparatus according to claim 2 wherein the chamber is adapted to contain the aerosolized medicament for subsequent delivery to a patient during a patient's inhalation.

6. An apparatus according to claim 2 wherein the chamber is cylindrical.

7. An apparatus according to claim 2 wherein the aerosolized medicament comprises small particles of medicament, the particles being sized to be deliverable to the alveolar regions of the lungs of a patient.

8. An apparatus according to claim 7 wherein the particles are predominantly 1 to 5 micrometers in diameter.

9. An apparatus according to claim 2 wherein at least 55 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

10. An apparatus according to claim 2 wherein at least 70 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

11. An apparatus for producing aerosolized medicament, the apparatus comprising:

a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide; and

a chamber comprising first and second air inlets and a mouthpiece, wherein the first and second air inlets are oriented so that gas may flow in a vortical flow path in the chamber and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament,

wherein the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber.

12. An apparatus according to claim 11 wherein the chamber volume is from 100 ml to 750 ml.

13. An apparatus according to claim 11 further comprising a source of compressed gas, wherein the compressed gas may be released from the source of compressed gas to cause the flow of gas to aerosolize the medicament.

14. An apparatus according to claim 11 wherein the chamber is adapted to contain the aerosolized medicament for subsequent delivery to a patient during a patient's inhalation.

15. An apparatus according to claim 11 wherein the chamber is cylindrical.

16. An apparatus according to claim 11 wherein the aerosolized medicament comprises small particles of medicament, the particles being sized to be deliverable to the alveolar regions of the lungs of a patient.

17. An apparatus according to claim 16 wherein the particles are predominantly 1 to 5 micrometers in diameter.

18. An apparatus according to claim 11 wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

19. An apparatus according to claim 11 wherein at least 70 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

20. An apparatus as in claim 2 wherein at least one of the inlets is oriented tangentially in the chamber.

21. An apparatus as in claim 2 wherein one of the inlets is not oriented tangentially in the chamber.

22. An apparatus as in claim 2 wherein the mouthpiece is oriented tangentially in the chamber.

23. An apparatus as in claim 11 wherein at least one of the inlets is oriented tangentially in the chamber.

24. An apparatus as in claim 11 wherein one of the inlets is not oriented tangentially in the chamber.

25. An apparatus as in claim 11 wherein the mouthpiece is oriented tangentially in the chamber.

26. An apparatus for producing aerosolized medicament, the apparatus comprising:

a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a systemically therapeutic protein or polypeptide; and

a chamber comprising an air inlet and a mouthpiece, wherein the air inlet is oriented so that gas may flow in a vortical flow path in the chamber and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament,

wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

27. An apparatus according to claim 26 wherein the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber.

28. An apparatus according to claim 26 wherein the chamber volume is from 100 ml to 750 ml.

29. An apparatus according to claim 26 further comprising a source of compressed gas, wherein the compressed gas may be released from the source of compressed gas to cause the flow of gas to aerosolize the medicament.

30. An apparatus according to claim 26 wherein the chamber is adapted to contain the aerosolized medicament for subsequent delivery to a patient during a patient's inhalation.

31. An apparatus according to claim 26 wherein the aerosolized medicament comprises small particles of medicament, the particles being sized to be deliverable to the alveolar regions of the lungs of a patient.

32. An apparatus according to claim 31 wherein the particles are predominantly 1 to 5 micrometers in diameter.

33. An apparatus according to claim 26 wherein at least 70 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

34. An apparatus as in claim 26 wherein the air inlet is oriented tangentially in the chamber.

35. An apparatus for producing aerosolized medicament, the apparatus comprising:

a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide; and

a chamber comprising a tangentially oriented air inlet and a non-tangentially oriented air inlet and a mouthpiece, wherein gas may flow into the chamber through the air inlets and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament,

wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

36. An apparatus according to claim 35 wherein the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber.

37. An apparatus according to claim 35 wherein the chamber volume is from 100 ml to 750 ml.

38. An apparatus according to claim 35 further comprising a source of compressed gas, wherein the compressed gas may be released from the source of compressed gas to cause the flow of gas to aerosolize the medicament.

39. An apparatus according to claim 25 wherein the chamber is adapted to contain the aerosolized medicament for subsequent delivery to a patient during a patient's inhalation.

(9) Evidence Appendix

none

(10) Related Proceedings Appendix

none